

EPA REG. JACKET 86794-4

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

June 3, 2014

OVERNIGHT DELIVERY

Katherine Montague (PM 23)
Document Processing Desk (FNL LBL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: NewAgco Inc.
MPower® Clodinafop-Propargyl Technical (EPA Reg. No. 86794-4)
Submission of Final Printed Label

Dear Ms. Montague,

On behalf of NewAgco Inc., I am submitting the final printed label for MPower® Clodinafop-Propargyl Technical in response to your letter dated May 7, 2014. In support of this submission, the following documents are enclosed:

1. Application for Registration (EPA Form 8570-1)
2. One (1) copy of the final printed label
3. Letter of authorization

Please contact me (phone (253) 853-7369; email Ann@PyxisRC.com) if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number NewAgco Inc./86794-4	2. EPA Product Manager K. Montague	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) NewAgco Inc./Mpower Clodinafop-Propargyl Technical	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) NewAgco Inc. c/o Pyxis Regulatory Consulting Inc. 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated May 17, 2014
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of final printed label.

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) lined fiber board drum
* Certification must be submitted			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 55.1, 110.2 lb	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Ann M. Tillman	Title Agent	Telephone No. (Include Area Code) (253) 853-7369	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 	3. Title Agent		
4. Typed Name Ann M. Tillman	5. Date 6/3/14		

MPOWER® CLODINAFOP-PROPARGYL TECHNICAL
FOR USE IN MANUFACTURING OR FORMULATING ONLY

ACTIVE INGREDIENT:	
Clodinafop-Propargyl*	98.5%
OTHER INGREDIENTS	1.5%
TOTAL	100.0%

*CAS No. 105512-06-9

KEEP OUT OF REACH OF CHILDREN
CAUTION

FIRST AID	
IF SWALLOWED	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 -20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.• Call a Poison Control Center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 -20 minutes.• Call a Poison Control Center or doctor for treatment advice.
IF INHALED	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice.
Have the product container or label with you when calling a poison control center, doctor, or going for treatment. For emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 seven days a week, 6:30 am to 4:30 pm Pacific Time (NPIC Web site: www.npic.orst.edu).	

EPA Reg. No. 86794-4

EPA Est. No. 87797-IND-00

Manufactured for:

NewAgco Inc.

Orena, St. Lawrence Main Road

Christ Church, Barbados BB15029

NET CONTENTS: 55.1 lbs (25 kg)

Batch No. See container

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Avoid contact with eyes or clothing.

[20140507]

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans or waters unless in accordance with the requirements of a National Pollutants Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This product may only be used to formulate herbicide end-use products with the following uses: (1) **Terrestrial Food Crops:** wheat; (2) uses for which US EPA has accepted the required data and/or citations of data that the formulator has submitted in the support of registration; (3) uses for experimental purposes that are in compliance with U.S. EPA requirements. Each formulator is responsible for obtaining EPA registration for his own end use products.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in original container tightly closed and in a safe place.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING: DRUM WITH INNER LINER: NONREFILLABLE CONTAINER: Do not reuse or refill this container. **INNER LINER:** Completely empty removable liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. Then dispose of empty liner in a sanitary landfill or by incineration or, if allowed by state and local authorities by burning. If burned, stay out of smoke. **DRUM:** Offer for recycling if available or dispose of drum in a sanitary landfill or by incineration or, if allowed by state and local authorities by burning. If burned, stay out of smoke. If drum is contaminated and cannot be reused, dispose of in the same manner required for its liner.

DISCLAIMER

The DIRECTIONS FOR USE of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and should be followed carefully. However, it is impossible to eliminate all risks inherently associated with use of this product. All such risks shall be assumed by the Buyer.

To the extent consistent with applicable law, NewAgco, Inc. or Seller shall not be liable for any incidental, consequential or special damages resulting from the use or handling of this product or THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF NEWAGCO, INC. AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF NEWAGCO, INC., OR SELLER, THE REPLACEMENT OF THE PRODUCT.

NewAgco, Inc. warrants only that the material contained herein conforms to the chemical description on the label and is reasonably fit for use therein described when used in accordance with the Directions for Use, subject to the risks referred to above. Any damage arising from a breach of this warranty shall be limited to direct damages and shall not include consequential or commercial damages, such as loss of profits or values or any other special or indirect damages. To the extent consistent with applicable law, NewAgco, Inc. makes no other express or implied warranty including any other express or implied warranty of FITNESS or MERCHANTABILITY. The sale of this product does not include a license under any patent owned by NewAgco, Inc.

Based On Draft Labeling Dated 5/7/14.
In Accordance with FRN Notice 82-2

MPOWER® CLODINAFOP-PROPARGYL TECHNICAL
FOR USE IN MANUFACTURING OR FORMULATING ONLY

ACTIVE INGREDIENT:

Clodinafop-Propargyl.....98.5%
OTHER INGREDIENTS.....1.5%
TOTAL.....100.0%

*CAS No. 105512-08-9

KEEP OUT OF REACH OF CHILDREN
CAUTION

FIRST AID

IF SWALLOWED	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 -20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.• Call a Poison Control Center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 -20 minutes.• Call a Poison Control Center or doctor for treatment advice.
IF INHALED	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice.
Have the product container or label with you when calling a poison control center, doctor, or going for treatment. For emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 seven days a week, 6:30 am to 4:30 pm Pacific Time (NPIC Web site: www.npic.orst.edu).	

EPA Reg. No. 86794-4

EPA Est. No. 87797-IND-00

Manufactured for:

NewAgco Inc.

Orena, St. Lawrence Main Road

Christ Church, Barbados BB15029

NET CONTENTS: 110.2 lbs (50 kg)

Batch No. See container

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Avoid contact with eyes or clothing.

[20140507]

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans or waters unless in accordance with the requirements of a National Pollutants Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This product may only be used to formulate herbicide end-use products with the following uses: (1) **Terrestrial Food Crops:** wheat; (2) uses for which US EPA has accepted the required data and/or citations of data that the formulator has submitted in the support of registration; (3) uses for experimental purposes that are in compliance with U.S. EPA requirements. Each formulator is responsible for obtaining EPA registration for his own end use products.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in original container tightly closed and in a safe place.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING: DRUM WITH INNER LINER: NONREFILLABLE CONTAINER: Do not reuse or refill this container. **INNER LINER:** Completely empty removable liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. Then dispose of empty liner in a sanitary landfill or by incineration or, if allowed by state and local authorities by burning. If burned, stay out of smoke. **DRUM:** Offer for recycling if available or dispose of drum in a sanitary landfill or by incineration or, if allowed by state and local authorities by burning. If burned, stay out of smoke. If drum is contaminated and cannot be reused, dispose of in the same manner required for its liner.

DISCLAIMER

The DIRECTIONS FOR USE of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and should be followed carefully. However, it is impossible to eliminate all risks inherently associated with use of this product. All such risks shall be assumed by the Buyer.

To the extent consistent with applicable law, NewAgco, Inc. or Seller shall not be liable for any incidental, consequential or special damages resulting from the use or handling of this product and THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF NEWAGCO, INC. AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF NEWAGCO, INC., OR SELLER, THE REPLACEMENT OF THE PRODUCT.

NewAgco, Inc. warrants only that the material contained herein conforms to the chemical description on the label and is reasonably fit for use therein described when used in accordance with the Directions for Use, subject to the risks referred to above. Any damage arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages, such as loss of profits or values or any other special or indirect damages. To the extent consistent with applicable law, NewAgco, Inc. makes no other express or implied warranty including any other express or implied warranty of FITNESS or MERCHANTABILITY. The sale of this product does not include a license under any patent owned by NewAgco, Inc.



June 16, 2011

To Whom It May Concern:

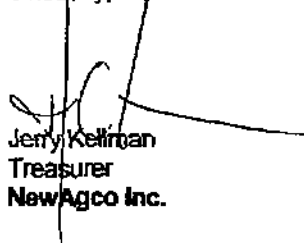
RE: Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Pyxis Regulatory Consulting, Inc. is authorized to act as agent for NewAgco Inc. (EPA Company Number 86794), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "JK", is written over the typed name and title.

Jerry Kellman
Treasurer
NewAgco Inc.

cc: Pyxis Regulatory Consulting, Inc.

Material Sent for Data Extraction

Reg. # 86794-4

Description: New Product

☐ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 5-7-14

☐ Notification Dated _____

☐ New CSF(s) Dated _____

☐ Other: _____

☐ Decision #: 479695

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Grant Rowland

Phone: 703-347-0254 Division: RD/HB/Team 23

Date: _____



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7504P)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

EPA Registration
Number:

86794-4

Date of Issuance:

MAY - 7 2014

Term of Issuance: **Unconditional**

Name of Pesticide Product:

**Mpower Clodinafop-Propargyl
Technical**

Name and Address of Registrant (include ZIP Code):

NewAgco, Inc.
c/o Pyxis Regulatory Consulting Inc.
4110 136th St. NW
Gig Harbor, WA 98332

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is registered in accordance with FIFRA sec 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration/reregistration review of your product when the Agency requires all registrants of similar products to submit data.
2. Make the following label revisions
 - a. Revise the EPA Reg No. to 86794-4
 - b. Assure that the establishment number and net content are also added to the label.
3. Data requirements for both storage stability (830.6317) and corrosion characteristics (830.6320) have not been satisfied. It is recommended that the observation be made at 0,3,6,9 and 12 month intervals. This data must be submitted within eighteen months of the date of this letter. The results must be submitted to the Agency in electronic and hard copy format.
4. Submit one copy of the revised final printed label before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

If you have any questions regarding the Notice, please contact Grant Rowland at (703) 347-0254 or rowland.grant@epa.gov.

Signature of Approving Official:

Kathryn Montague
Product Manager 23
Herbicide Branch
Registration Division (7505P)

Date:

MAY - 7 2014

MPOWER® CLODINAFOF-PROPARGYL TECHNICAL

FOR USE IN MANUFACTURING OR FORMULATING ONLY

ACTIVE INGREDIENT:
Clodinafop-Propargyl*.....98.5%
OTHER INGREDIENTS.....1.5%
TOTAL.....100.0%

*CAS No. 105512-06-9

KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID	
IF SWALLOWED	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
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EPA Reg. No. 86794-U

EPA Est. No.

NET CONTENTS:

Manufactured for:
NewAgco Inc.
Orena, St. Lawrence Main Road
Christ Church, Barbados BB15029

MAY - 7 2014

86794-4

**PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS AND DOMESTIC ANIMALS
CAUTION**

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Avoid contact with eyes or clothing.

ENVIRONMENTAL HAZARDS

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DIRECTIONS FOR USE

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To the extent consistent with applicable law, NewAgco, Inc. makes no other express or implied warranty including any other express or implied warranty of FITNESS or MERCHANTABILITY. The sale of this product does not include a license under any patent owned by NewAgco, Inc.

[20140507]

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

May 21, 2013

OVERNIGHT DELIVERY

Katherine Montague (PM 23)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: NewAgco Inc.
MPower® Clodinafop-Propargyl Technical (EPA File Symbol 86794-)
Application for New Pesticide Registration
PRIA Category R334 (Primary Application)

Dear Ms. Montague,

On behalf of NewAgco Inc., we are submitting an application for registration of MPower® Clodinafop-Propargyl Technical, a new manufacturing use product containing the active ingredient Clodinafop-propargyl. This action is linked to the application for registration of MPower® Clodinafop Herbicide, an end use product that contains MPower® Clodinafop-Propargyl Technical as the source of active ingredient.

NewAgco Inc. would like to point out that the data submitted with this application are exactly the same data that PMRA has reviewed and approved for NewAgco's Clodinafop-Propargyl Herbicide Technical (Registration Number 29424).

In support of this application, we submit the following documents:

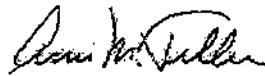
1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4)
3. Three (3) Copies of the Proposed Labeling
4. A CD containing an electronic version of the proposed labeling
5. Certification with Respect to Label Integrity
6. Certification with Respect to Citation of Data (EPA Form 8570-34)
7. Agency Internal Use Copy of the Data Matrix
8. Public File Copy of the Data Matrix
9. Signed Small Business Certification for PRIA fee reduction
10. Copy of PRIA payment
11. Letter of Authorization
12. Copy of submission cover letter for the secondary application for MPower® Clodinafop Herbicide
13. Product Specific Data (3 copies of each report);

49133301	Volume 1	830.1550, 830.1600, 830.1620, 830.1670, 830.1750	Tillman, A. M. Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, and Certified Limits for MPower® Clodinafop-Propargyl Technical. <i>Contains Confidential Business Information.</i>
49133302	Volume 2	830.1700, 830.1800	Patel, A. H. Preliminary Analyses of Five Representative Production Batches of Clodinafop-Propargyl Technical Grade Active Ingredient (TGAI) to Determine % Clodinafop-Propargyl. <i>Contains Confidential Business Information.</i>
49133303	Volume 3	CIPAC MT 30.5	Bhandari, N. M. Moisture Content of Clodinafop-Propargyl Technical.
49133304	Volume 4	830.1700, 830.1800	Vohra, J. Preliminary Analyses of Five Representative Production Batches of Clodinafop-Propargyl Technical Grade Active Ingredient (TGAI) to Determine % Clodinafop-Propargyl and to Quantify its Associated Impurities. <i>Contains Confidential Business Information.</i>
49133305	Volume 5	CIPAC 683.225/TC/M/3.2	Patel, A. H. Determination of R and S Ratio in Five Representative Production Batches of Clodinafop-Propargyl Technical Grade Active Ingredient (TGAI).
49133306	Volume 6	830.1800	Parmar, J. M. Validation of Analytical Method for Active Ingredient Analysis of Clodinafop-Propargyl Technical by HPLC.
49133307	Volume 7	830.6302, 830.6303, 830.6304, 830.6313, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7050, 830.7100, 830.7200, 830.7370, 830.7520, 830.7550-7570, 830.7840-7860, 830.7950	Tillman, A. M. Clodinafop-Propargyl Technical: Physical and Chemical Properties and Waiver Requests.
49133308	Volume 8	830.6314	Rana, M. Oxidation/Reduction: Chemical Incompatibility Properties of Clodinafop-Propargyl Technical.
49133309	Volume 9	830.7000	Desai, H. pH of Clodinafop-Propargyl Technical.
49133310	Volume 10	830.7300	Vohra, H. Specific Gravity of Clodinafop-Propargyl Technical.
49133311	Volume 11	830.7950	Vohra, H. Vapour Pressure of Clodinafop-Propargyl Technical.
49133312	Volume 12	870.1100	Shinde, K. Acute Oral Toxicity Study of Clodinafop-Propargyl Technical in Rats.
49133313	Volume 13	870.1200	Shinde, K. Acute Dermal Toxicity Study of Clodinafop-Propargyl Technical in Rats.
49133314	Volume 14	870.2400	Shinde, K. Acute Eye Irritation Study of Clodinafop-Propargyl Technical in Rabbits.
49133315	Volume 15	870.2500	Shinde, K. Acute Dermal Irritation Study of Clodinafop-Propargyl Technical in Rabbits.
49133316	Volume 16	870.2600	Shinde, K. Skin Sensitization Study of Clodinafop-Propargyl Technical in Guinea Pigs [Guinea Pig Maximization Test].

NewAgco Inc. is using the selective method of data citation. As per EPA's interpretations of 40 CFR Parts 152.86(b)(2)(i) and 152.93(b)(2)(i), NewAgco Inc. submitted notices of intent to apply and offers to pay to all companies on the April 8, 2013 Data Submitter's List. This action falls under PRIA category R334 (53: New manufacturing use product) because it is an application for registration of an unregistered source of active ingredient using selective data citation. The fee for this action is \$17,993, but NewAgco Inc. is requesting a 50% PRIA fee reduction to \$8,997. Documentation to support eligibility as a small business was submitted previously (February 2013) and a signed Small Business Certification for this submission is enclosed.

We trust you will find this application complete. However, please feel free to contact me (253-855-7369, Ann@PyxisRC.com) if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

Sub-DP BARCODE No.: D413643; PARENT BEAN: D413554; FILE SYMBOL No.: 86794-U(screen);
PRODUCT NAME: MPower Clodinafop-Propargyl Technical; DECISION No.: 479095; PC Code(s): 125203;
ACTION CODE: R334; FOOD Use: Yes

DATE OUT: July 30, 2013

SUBJECT: Completeness check screening for "MPower Clodinafop-Propargyl Technical" TGAI/MUP

FROM: Shyam Mathur,
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

Shyam Mathur 7/30/13

TO: Grant Rowland / Kathryn Montague, RM 23
Herbicide Branch / RD (7505P)

Company Name: Newagco Incorporation
Formulation Type: Herbicide

Results of completeness check screen

File No./ Reg. No	Product Name	Group A Data Submitted		Group B Data Submitted		CSF		Label
		Yes	No	Yes	No	Yes	No	
86794-U	MPower Clodinafop- Propargyl technical	+		+		+	Basic dated 10-04-12	+

CONCLUSION:

Group A: All data submitted

Group B: Data submitted.

CSF: Basic CSF (dated 10-04-12) submitted

Product label: Submitted

MRID Nos. 491702-01 to 491702-05



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DATE OUT: 02 / APRIL / 2014

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MP [X] EP []**
DP BARCODE No.: DP413554 EPA Reg. No.: 86794-U
PRODUCT NAME: Mpower Clodinafop-Propargyl Technical
COMPANY: NewAgco, Inc.
FOOD USE [Yes] **INTEGRATED FORMULATION [X]**
PCC: 125203 Decision No. 479095
ACTION CODE: R334 Pesticidal use: Herbicide

FROM: Hari Mukhoty, DVM, PhD
Product Chemistry Team
Technical Review Branch / RD (7505P)

TO: Grant Rowland, CRM / Kathryn Montague, RM 23
Herbicide Branch / RD (7505P)

Handwritten signatures and date:
[Signature] [Signature] 4/7/14

INTRODUCTION:

The registrant has submitted a technical basic CSF (Dated: 10/04/2012) and a product specific label for registration of the aforesaid product under EPA File Symbol. No. 86794-U. Product chemistry data have been submitted under MRIDs: 491333-01 through -11.

The aforesaid TGA/MP is manufactured by [REDACTED] for the registrant NewAgco, Inc. located in Barbados.

Label text indicates that this proposed MUP is intended to be formulated into end-use products with food uses & other products with uses approved by EPA.

TRB has been requested to evaluate the product chemistry data required for the registration of the proposed MP.

SUMMARY OF FINDINGS:

1. The proposed TGA/MP contains the active ingredient: Clodinafop-propargyl (98.5%).
2. The overall mean of the active ingredient from the five batch analysis is 98.23% [MRID: 491333-02, Page 23] through 99.82% [MRID: 491333-04 Page 15].
3. The proposed nominal concentration of the active ingredient in the MP is 98.5 %. The nominal concentration of the active ingredient matches with the label claim. This is in compliance with PR Notice 91-2. The certified limits stated in the TGA/MP basic CSF (Dated: 10/04/ 2013) for the active ingredient and the associated impurities have been described in the aforesaid submitted CSF.

DP BARCODE No.: 413554 **EPA File Symbol No.:** 86794-U **PRODUCT NAME:** Mpower Clodinafop Propargyl Technical

4. This basic CSF has been reviewed by I.I.A. Branch on 05/30/2013 and they stated that the product is a Technical containing only impurities and no inerts.

5. The product chemistry data submitted for Group A corresponding to guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product), 830.1620 (description of production process), 830.1670 (discussion of formation of impurities), 830.1750 (certified limits) satisfy the product chemistry data requirements of 40 CFR §158.320, 158.325, 158.330, 158.340, and 158.350 respectively for the proposed formulation [MRID: 491333-01].

6. The analytical methods used to quantify and identify the active ingredient and the impurities are: HPLC method using UV-VIS detector set at 305 nm. LS-MS was also used to characterize the active ingredient. Karl Fischer apparatus was used to quantify water content of the formulation (MRID: 491133-02, -03, -04 and -06).

The method to determine the content of active ingredient was validated with respect to selectivity, system precision, and linearity of response, range of linearity, assay accuracy and method precision (MRID: 491133-02).

Similar analytical techniques can also be applied for Enforcement Analytical Method (MRID: 491133-02, -04).

7. Product chemistry Group A and Group B data, with the exception of Storage Stability (830.6317) and Corrosion Characteristics (830.6320) data requirements are satisfied.

8. There were no known impurities of toxicological significance in the technical formulation (MRID: 491333-01).

9. The total % of R and S isomers was (99.59 – 99.68% R) and 0.33 – 42% S) [MRID: 4911333-05]. .

DP BARCODE No.: 413554 **EPA File Symbol No.:** 86794-U **PRODUCT NAME:** Mpower Clodinafop
Propargyl Technical

CONCLUSIONS:

1. TRB has reviewed the proposed TGA/MP basic CSF (dated: 10/04/2012) and has found it to be acceptable. The CSF is attached with this review and can be located in OPPIN CHEM DOCS.
2. Product chemistry Group A data and Group B data, with the exception of Storage Stability (830.6317) and Corrosion Characteristics (830.6317) are acceptable.
3. The registrant must generate one year storage stability (830.6317) and Corrosion Characteristics (830.6317) data on the proposed product. It is required that the observations be made at 0, 3, 6, 9, and 12 month intervals. The results must be submitted to the Agency in electronic and hard copy format.

DP BARCODE No.: 413554 **EPA File Symbol No.:** 86794-U **PRODUCT NAME:** Mpower Clodinafop Propargyl Technical

PRODUCT CHEMISTRY DATA (SERIES 830 Group A)

Group A	Data Required Fulfilled	MRID No.
830.1550. Chemical Identity (same as in Product CSF dated 10/04/2012)	A	491333-01
830.1600. Beginning Materials	A	"
830.1620. Production process	A	"
830.1650. Formulation process	NA	
830.1670. Discussion of Impurities	A	"
830.1700. Preliminary Analysis	A	491333-02, -03, -04 and -06
830.1750. Certified Limits	A	"
830.1800. Enforcement Analytical Method	A	"

A = Acceptable NA = Not Applicable

DP BARCODE No.: 413554 EPA File Symbol No.: 86794-U PRODUCT NAME: Mpower Clodinafop Propargyl Technical

Table 2: Physical and Chemical Properties of: Mpower Clodinafop Propargyl Technical

GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	491333-07	A	White
830.6303	Physical state	"	A	Powder (Solid)
830.6304	Odor	"	A	Odorless
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	"	A	Stable for 14 days to normal and elevated (54°C) temperatures as determined also with metals or metal ions.
830.6314	Oxidation/reduction: chemical incompatibility	"	A	It was found to be compatible with water, Zinc dust, potassium permanganate, and kerosene and monoammonium phosphate.
830.6315	Flammability	"	A	It is a solid and is not expected to be flammable
830.6316	Explosibility	"	A	Not explosible
830.6317	Storage stability	"	G	
830.6319	Miscibility	"	NA	
830.6320	Corrosion characteristics	"	G	
830.7000	pH	"	A	6.3 – 6.4 @ 20.7°C
830.7050	UV/Visible absorption	"	A	UV-Vis absorption was determined at pH < 2 through > 10,
830.7100	Viscosity	"	NA	
830.7200	Melting point	"	A	54.8- 58.0 °C
830.7220	Boiling point	"	NA	
830.7300	Density	"	A	1.39 g/m ³
830.7370	Dissociation constants in water (DC)	"	A	Does not have a functional group to dissociate.
830.7550	Partition coefficient	"	A	Log Pow = 3.9 Calculated value
830.7840	Water solubility	"	A	Led to about 22% hydrolysis. Reliable value could not be obtained. Cited: water solubility is 4 mg/ L, in n-heptane < 10 g/L, 192-240 g/L in methanol, > 240 g/L in dichloromethane, ethyl acetate, toluene & acetone.
830.7950	Vapor pressure	"	A	Cited: 0.3×10^{-5} calculated 1×10^{-5}

A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress ;
U = Up-grade (additional information required); W = waivers

Manufacturing process information may be entitled to confidential treatment

DP BARCODE No.: 413554 **EPA File Symbol No.:** 86794-U **PRODUCT NAME:** Mpower Clodinafop
Propargyl Technical

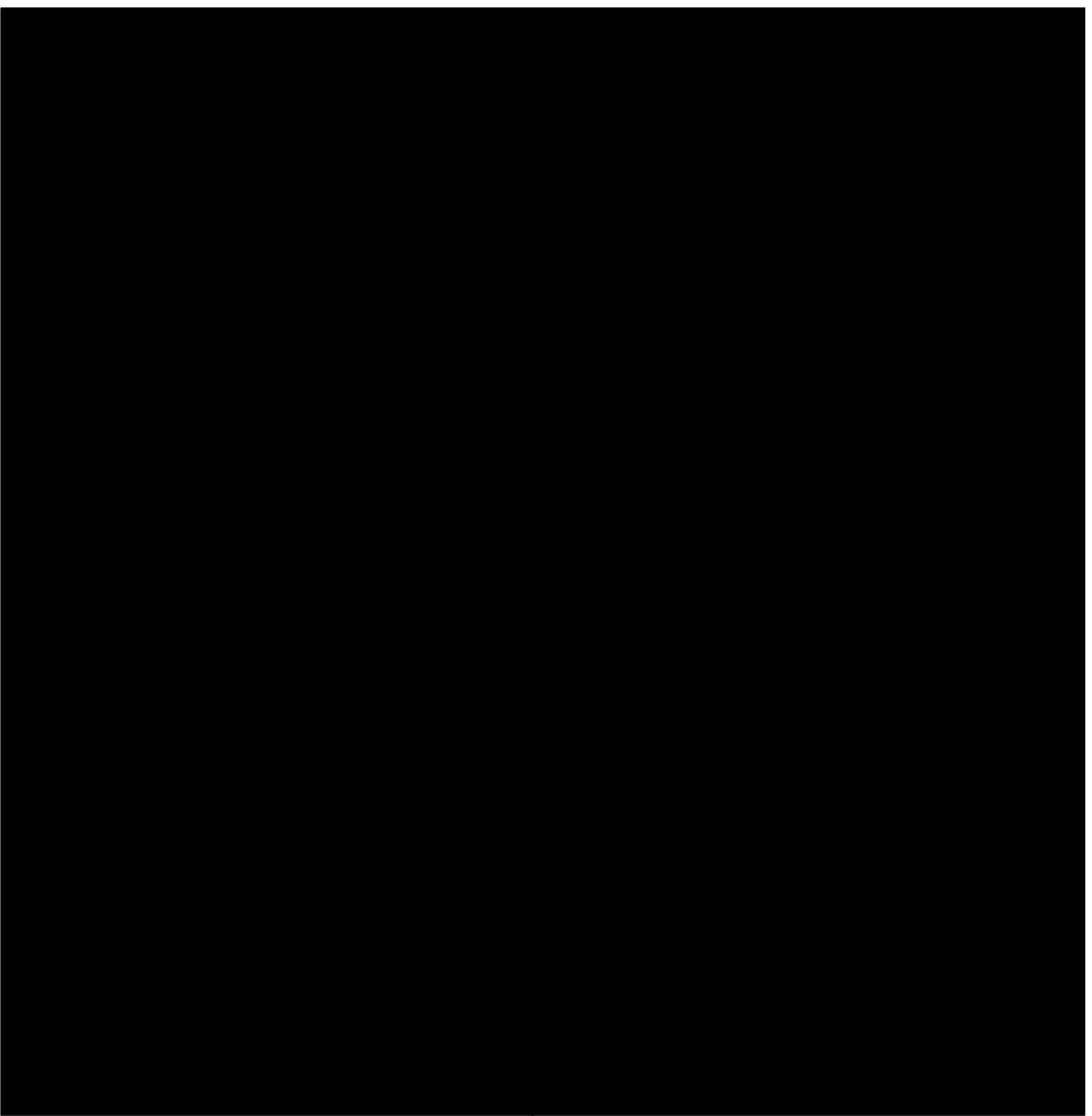
CONFIDENTIAL APPENDIX



Manufacturing process information may be entitled to confidential treatment

DP BARCODE No.: 413554 **EPA File Symbol No.:** 86794-U **PRODUCT NAME:** Mpower Clodinafop
Propargyl Technical

CONFIDENTIAL APPENDIX





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

04/01/2014

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No. 86794-U
Product Name: Mpower Clodinafop-Propargyl Technical
DP Barcode: 413558
Decision No: 479095
Action Code: R334
PC Code: 125203

From: Santa K Vinjamuri M.D., D.C.P. *Bentaz*
Inert Ingredient Assessment Branch (IIAB)
Registration Division (7505P)

Through: Technical Review Branch (TRB)
Registration Division (7505P)

*W/Haslin
Team Leader / Tox*

To: Grant Rowland/Kathryn Montague, RM Team 23
Insecticide-Rodenticide Branch
Registration Division (7505P)

Applicant: NewAgco, Inc.
Orena, St. Lawrence Main Road
Christ Church Barbados BB 15029

FORMULATION FROM EPA Reg. No. 86794-U, LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Clodinafop-propargyl :	98.5
<u>Inert Ingredient(s):</u>	1.5
Total	100.0

PC Code(s) 125203

EPA Reg. No. / File Symbol: 86794-U

ACTION REQUESTED: The Risk Manager requests "The registrant has submitted tox studies, to support a new technical product. The action is linked to another product (86794-L) which was withdrawn but there may be studies linked to the withdrawn product that supports this action. Please review the studies and cross reference with the withdrawn products studies to determine if this product passes tox screening."

Included in the package are copies of the data matrix, letter from the registrant, proposed label, basic CSF dated 10/4/2012 and application for the cited Reg 100-909 dated 5/21/2013.

BACKGROUND: NewAgco, Inc. (herein the "registrant") in their letter stated that [REDACTED] is an approved inert ingredient for use in pesticide formulations which is used in their present end use product MPower Clodinafop Herbicide. As they are obtaining this ingredient from a new source, the registrant is submitting data to support its use along with the application for registration of the product.

Accordingly the registrant is submitting acute toxicity studies MRID's: 49133312 to 49133316 (oral, dermal, primary skin irritation & eye irritation and dermal sensitization studies) and citing MRID: 44399126 for acute Inhalation toxicity.

MRID: 44399126 was reviewed (txr 0013787; Reg No: 100-909) and classified as toxicity category IV(acceptable /Guidline) wide memo dated 10/06/99 by HED. The test substance used was Clodinafop Propargyl Technical. (Citation: Hartmann, H. (1987) Acute Aerosol Inhalation Toxicity in the Rat: CGA-184927: Lab Project Number: 871017: 199-87. Unpublished study prepared by Novartis Crop Protection AG. 25 p). The Agency will allow the subject product to cite this study.

COMMENTS & RECOMMENDATIONS:

1. The Five studies; MRID's: 49133312 to -49133316 conducted with the test substance "Clodinafop-Propargyl Technical" were reviewed and are acceptable.
2. The cited acute Inhalation toxicity (81-3) is acceptable
3. These studies satisfy the acute toxicity data requirements for the registration of EPA File Symbol 86794-U
4. The Basic Formulation CSF dated 10/04/2012 for the proposed product should also be reviewed and accepted by the TRB Product Chemistry Team.
5. The label states that the present product "Mpower Clodinafop-Propargyl Technical" is for manufacturing or formulating use only.
6. Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

(Continued on the next page)

Precautionary Labeling:

PRODUCT ID #: 086794-00004

PRODUCT NAME: MPOWER CLODINAFOP-PROPARGYL TECHNICAL

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals*:

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using toilet. Avoid contact with eyes or clothing. *Wear protective eyewear. *Wear: Long-sleeved shirt and long pants, Socks, Shoes, and gloves.

*The designation of Personal Protective Equipment (PPE) for manufacturing use products does not fall under the jurisdiction of EPA; therefore, PPE is optional for this product.

First Aid:

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

(Continued on the next page)

DATA EVALUATION RECORD**Product Reg. No.: 86794-U****Product Name: MPOWER CLODINAFOF-PROPARGYL TECHNICAL**

1. DP BARCODE: 413558				
2. PC CODE: 125203				
3. CURRENT DATE: 4/01/2014				
4. TEST MATERIAL: Clodinafop-Propargyl Technical (Propynyl(R)-2-[4-(5-chloro-3-fluoro-2-pyridinyl)oxy]=phenoxy]propanoate; Batch #: 2365, Off-white solid.				
Study/Species/Lab Lab Project ID: /Date	MRID	Results	Tox Cat	Grade
Acute oral toxicity/ rat/ Class Method/ Jai Research Foundation Department of Toxicology/ Study #: 6965 /11-05- 2007/Guideline number: OPPTS 870.1100; OECD 425	49133312	Oral LD ₅₀ in female rats is 1750 mg/kg bw. Mortality 2/2 at 2,600 mg/kg & 1/1 at 2000 mg/kg, 1/3 at 1750, mg/kg bw dose levels. clinical signs included, lethargy, piloerection & Lacrimation. Enlarged liver with rounded edges & mottling, pallor spleen, and intestinal congestion were noted in found dead rats. No abnormalities were noted in any of the terminally sacrificed rats at necropsy.	III	A
Acute dermal toxicity/ rat, /Jai Research Foundation Department of Toxicology/ Study #: 6965 /11-23- 2007/ Guideline number: OPPTS 870.1200; OECD guideline 402.	49133313	LD ₅₀ - Male & Female rats > 5,000 mg/kg. No mortality (0/10) & no signs of systemic toxicity. No gross abnormalities were noted at necropsy.	IV	A
Acute Aerosol Inhalation Toxicity/Rat/ Hartmann, H./ Lab Project Number: 871017: 199-87	44399126	LC ₅₀ Male and female rats > 2.3 mg/L (txr #: 0013787; memo dated 10/06/99; Reg No: 100-909)	IV	C
Primary eye irritation / rabbit/ Jai Research Foundation Department of Toxicology/ Study #: 6968 /11-05-2007/ Guideline number: OPPTS 870.2400; OECD guideline 405	49133314	Mildly irritating to the rabbit eye. No corneal opacity or iritis in any of the treated eyes. Conjunctivitis 3/3 was noted at 24 hours. The overall incidence & severity of irritation cleared within 48 hours.	III	A

(Continued on the next page)

Primary dermal irritation / rabbit/ Jai Research Foundation Department of Toxicology/ Study #: 6967 /11-05- 2007. /Guideline number: OPPTS 870.2500; OECD guideline 404.	49133315	Non irritating to the skin. No erythema or edema was observed in any of the test sites. No toxic signs were observed in any of the rabbits tested. Primary Dermal Irritation Index (PDII) is 0.0 based dermal irritation scores from 1 hour to 72 hours.	IV	A
Dermal sensitization- (maximization test) Guinea pigs/ Jai Research Foundation Department of Toxicology/study# 6969/ December 29, 2007/Guideline number: OPPTS 870.2600; OECD guideline 406	49133316	Negative (not a sensitizer) The intradermal induction in the test group was performed with 1% concentration of the test item (Clodinafop-propargyl technical in propylene glycol). 100mg of the test item(moistened with 0.2ml of 80% ethanol) was selected for topical application. Very slight to well-defined erythema & very slight edema was observed in the treatment group following both intradermal & topical application during induction. No irritation was observed in the control group. Challenge exposure did not reveal any positive skin response either in treatment or control groups. Positive response observed with α -Hexylcinnamaldehyde (α -HCL) JRF study # 7000 from Aug 20 to Oct 17 2007, validates the test system.	Negative	A

Grade Key: A =Acceptable, U = Unacceptable, D = Data Gap, C= cited


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

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DATA MATRIX

Date May 21, 2013			EPA Reg. No./File Symbol 86794-		Page 1 of 13
Applicant's/Registrant's Name & Address NewAgco, Inc. Orena, St. Lawrence Main Road Christ Church Barbados BB 15029			Product MPower® Clodinafop-Propargyl Technical		
Ingredient Clodinafop-propargyl (CAS No. 105512-06-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Requirements					
830.1550	Product Identity and Composition	Volume 1	NewAgco, Inc.	OWN	
830.1600	Description of Materials Used to Produce the Product	Volume 1	NewAgco, Inc.	OWN	
830.1620	Description of Production Process	Volume 1	NewAgco, Inc.	OWN	
830.1650	Description of Formulation Process				Not Required ¹
830.1670	Discussion of Formation of Impurities	Volume 1	NewAgco, Inc.	OWN	
830.1700	Preliminary Analysis	Volume 2 Volume 3 Volume 4 Volume 5	NewAgco, Inc. NewAgco, Inc. NewAgco, Inc. NewAgco, Inc.	OWN OWN OWN OWN	
830.1750	Certified Limits	Volume 1	NewAgco, Inc.	OWN	
830.1800	Enforcement Analytical Method	Volume 6	NewAgco, Inc.	OWN	
830.6302	Color	Volume 7	NewAgco, Inc.	OWN	
830.6303	Physical State	Volume 7	NewAgco, Inc.	OWN	
Signature 			Name and Title Ann M. Tillman, Consultant		Date May 21, 2013


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DATA MATRIX

Date May 21, 2013			EPA Reg. No./File Symbol 86794-		Page 2 of 13
Applicant's/Registrant's Name & Address NewAgco, Inc. Orena, St. Lawrence Main Road Christ Church Barbados BB 15029			Product MPower® Clodinafop-Propargyl Technical		
Ingredient Clodinafop-propargyl (CAS No. 105512-06-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6304	Odor	Volume 7	NewAgco, Inc.	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	Volume 7 Volume 7	NewAgco, Inc. NewAgco, Inc.	OWN OWN	Data Waiver ²
830.6314	Oxidation/Reduction: Chemical Incompatibility	Volume 8	NewAgco, Inc.	OWN	
830.6315	Flammability	Volume 7	NewAgco, Inc.	OWN	Waiver ³
830.6316	Explosibility	Volume 7	NewAgco, Inc.	OWN	Waiver ⁴
830.6317	Storage Stability	Volume 7	NewAgco, Inc.	OWN	PRN 92-5 ⁵
830.6319	Miscibility				Not Required ⁶
830.6320	Corrosion Characteristics	Volume 7	NewAgco, Inc.	OWN	PRN 92-5 ⁵
830.6321	Dielectric Breakdown Voltage				Not Required ⁶
830.7000	pH	Volume 9	NewAgco, Inc.	OWN	
830.7050	UV/Visible Absorption	Volume 7	NewAgco, Inc.	OWN	
830.7100	Viscosity				Not Required ⁶
830.7200	Melting Point/Melting Range	Volume 7	NewAgco, Inc.	OWN	
830.7220	Boiling Point/Boiling Range				Not Required ⁷
Signature 			Name and Title Ann M. Tillman, Consultant		Date May 21, 2013


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DATA MATRIX

Date May 21, 2013			EPA Reg. No./File Symbol 86794-		Page 3 of 13
Applicant's/Registrant's Name & Address NewAgco, Inc. Orena, St. Lawrence Main Road Christ Church Barbados BB 15029			Product MPower® Clodinafop-Propargyl Technical		
Ingredient Clodinafop-propargyl (CAS No. 105512-06-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7300	Density/Relative Density/Bulk Density	Volume 10	NewAgco, Inc.	OWN	
830.7370	Dissociation Constants in Water	Volume 7	NewAgco, Inc.	OWN	
830.7520	Particle Size, Fiber Length, and Diameter Distribution				Not Required ⁵
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method	Volume 7	NewAgco, Inc.	OWN	
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7550
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7550
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	Volume 7	NewAgco, Inc.	OWN	
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure	Volume 7 Volume 11	NewAgco, Inc. NewAgco, Inc.	OWN OWN	
Signature 			Name and Title Ann M. Tillman, Consultant		Date May 21, 2013


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Applicant's/Registrant's Name & Address NewAgco, Inc. Orena, St. Lawrence Main Road Christ Church Barbados BB 15029			Product MPower® Clodinafop-Propargyl Technical		
Ingredient Clodinafop-propargyl (CAS No. 105512-06-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	Acute Oral Toxicity: Rat	Volume 12	NewAgco, Inc.	OWN	
870.1200	Acute Dermal Toxicity: Rat	Volume 13	NewAgco, Inc.	OWN	
870.1300	Acute Inhalation Toxicity: Rat	44399126		OLD	
870.2400	Primary Eye Irritation: Rabbit	Volume 14	NewAgco, Inc.	OWN	
870.2500	Primary Dermal Irritation	Volume 15	NewAgco, Inc.	OWN	
870.2600	Dermal Sensitization	Volume 16	NewAgco, Inc.	OWN	
Generic Data Requirements					
850.2100 (71-1)	Acute Avian Oral Toxicity	Cite-all		PAY	
850.2200 (71-2)	Avian Dietary Toxicity	Cite-all		PAY	
850.2300 (71-4)	Avian Reproduction	Cite-all		PAY	
850.2400 (71-3)	Wild Mammal Toxicity				Not required
850.1075 (72-1)	Freshwater Fish Toxicity	Cite-all		PAY	
850.1010 (72-2)	Freshwater Invertebrate Toxicity	Cite-all		PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date May 21, 2013


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Ingredient Clodinafop-propargyl (CAS No. 105512-05-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1025, 850.1035, 850.1045, 850.1055, 850.1075 (72-3(a,b,c))	Estuarine/Marine Toxicity: Fish, Mollusk and Shrimp				Not required ⁸
850.1300 (72-4)	Aquatic Invertebrate Life Cycle (Freshwater)	Cite-all		PAY	
850.1350	Aquatic Invertebrate Life Cycle (Saltwater)				Not required ⁹
850.1400 (72-4)	Fish Early-life Stage (Freshwater)			GAP	
850.1400	Fish Early-life Stage (Saltwater)				Not required ¹⁰
850.1500 (72-5)	Fish Life Cycle				Not required ¹¹
850.1710, 850.1730, 850.1850 (165-4)	Aquatic Organisms Bioavailability, Biomagnification, Toxicity	Cite-all		PAY	
850.1950	Simulated or Actual Field Testing for Aquatic Organisms				Not required
850.1735	Whole Sediment; Acute Freshwater Invertebrates				Not required
850.1735	Whole Sediment; Acute Marine Invertebrates				Not required
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Ingredient Clodinafop-propargyl (CAS No. 105512-06-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.3020 (141-1)	Honeybee Acute Contact Toxicity	Cite-all		PAY	
850.3030	Honeybee Toxicity of Residues on Foliage				Not required ¹²
850.3040	Field Testing for Pollinators				Not required ¹³
850.4100 (122-1(a))	Tier 1: Seed Germination/Seedling Emergence	Cite-all		PAY	
850.4150 (122-1(b))	Tier 1: Vegetative Vigor	Cite-all		PAY	
850.4400 (122-2)	Tier 1: Aquatic Plant Growth	Cite-all		PAY	
850.4100 (122-1(a))	Tier 2: Seed Germination/Seedling Emergence	Cite-all		PAY	
850.4150 (123-1(b))	Tier 2: Vegetative Vigor	Cite-all		PAY	
850.4400 (123-2)	Tier 2: Aquatic Plant Growth	Cite-all		PAY	
870.6100 (81-8)	Acute Neurotoxicity - Rat	46012922 46012947	Syngenta Crop Protection Syngenta Crop Protection	PAY PAY	See endnote ¹⁴
870.3100 (82-1)	90-Day Oral - Rodent	44399130 44399132		OLD OLD	See endnote ¹⁵
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Ingredient Clodinafop-propargyl (CAS No. 105512-06-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.3150 (82-1)	90-Day Oral - Non-rodent	44399139		OLD	See endnote ¹⁶
870.3200 (82-2)	21/28-Day Dermal	44399141		OLD	See endnote ¹⁷
870.3250	90-Day Dermal				Not required ¹⁸
870.3465	90-Day Inhalation				Not required ¹⁹
870.6200 (82-5(a))	90-Day Neurotoxicity - Rat	46012921	Syngenta Crop Protection	PAY	See endnote ²⁰
		46012946	Syngenta Crop Protection	PAY	
870.4100 (83-1)	Chronic Feeding: Rat	44399147		OLD	See endnote ²¹
83-1(b)	Chronic Feeding: Dog				Not required ²²
870.4200 (83-2)	Carcinogenicity - Rat and Mouse	44399143		OLD	See endnote ²³
		44399147		OLD	
870.3700 (83-3)	Prenatal Developmental Toxicity - Rat and Rabbit	44399144		OLD	See endnote ²⁴
		44399145		OLD	
870.3800 (83-4)	Reproduction and Fertility Effects	44399146		OLD	See endnote ²⁵
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Ingredient Clodinafop-propargyl (CAS No. 105512-06-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.6300	Developmental Neurotoxicity	46012925 46012948 47085301	Syngenta Crop Protection Syngenta Crop Protection Syngenta Crop Protection	PAY PAY PAY	See endnote ²⁶
870.5100, 870.5200 (84-2(a))	Bacterial Reverse Mutation Assay	44399153 44399152		OLD OLD	See endnote ²⁷
870.5550	DNA Repair	44399156		OLD	See endnote ²⁸
870.5395	Micronucleus Test	44399151		OLD	See endnote ²⁹
870.7485 (85-1)	Metabolism and Pharmacokinetics	44399159 44399160		OLD OLD	See endnote ³⁰
870.7600 (85-2)	Dermal Penetration				Not required ³¹
870.7800	Immunotoxicity			GAP	
875.1100	Dermal Outdoor Exposure	Cite-all		PAY	
875.1200	Dermal Indoor Exposure				Not required
875.1300	Inhalation Outdoor Exposure	Cite-all		PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date May 21, 2013


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Ingredient Clodinafop-propargyl (CAS No. 105512-06-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.1400	Inhalation Indoor Exposure				Not required
875.1500	Biological Monitoring				Not required
875.1600	Data Reporting and Calculations				Not required
875.1700	Product Use Information				Not required
875.2100 (132-1a)	Foliar Residue Dissipation	Cite-all		PAY	
875.2200	Soil Residue Dissipation	Cite-all		PAY	
875.2300	Indoor Surface Residue Dissipation				Not required
875.2400 (133-3)	Dermal Passive Dosimetry Exposure	Cite-all		PAY	
875.2500 (133-4)	Inhalation Passive Dosimetry Exposure	Cite-all		PAY	
835.2120 (161-1)	Hydrolysis	Cite-all		PAY	
835.2240 (161-2)	Photodegradation in Water	46012927 46012928	Syngenta Crop Protection Syngenta Crop Protection	PAY PAY	See endnote ³²
835.2410 (161-3)	Photodegradation on Soil	Cite-all		PAY	
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Ingredient Clodinafop-propargyl (CAS No. 105512-06-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.4100 (162-1)	Aerobic Soil Metabolism	46012930 46012931	Syngenta Crop Protection Syngenta Crop Protection	PAY PAY	See endnote ³³
835.4200 (162-2)	Anaerobic Soil Metabolism	Cite-all		PAY	
835.4300 (162-4)	Aerobic Aquatic Metabolism	44387449 44399177 44399178		OLD OLD OLD	See endnote ³⁴
835.4400 (162-3)	Anaerobic Aquatic Metabolism	46012932 46012933	Syngenta Crop Protection Syngenta Crop Protection	PAY PAY	See endnote ³⁵
835.1230, 835.1240 (163-1)	Leaching and Adsorption/Desorption	44399182 46012935 46012937 46012934 46012936	Syngenta Crop Protection Syngenta Crop Protection Syngenta Crop Protection Syngenta Crop Protection	OLD PAY PAY PAY PAY	See endnote ³⁶
835.1410 (163-2)	Lab Volatility				Not required ³⁷
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Ingredient Clodinafop-propargyl (CAS No. 105512-06-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.6100 (164-1)	Terrestrial Field Dissipation Study	46012939 46373401 46012938	Syngenta Crop Protection Syngenta Crop Protection Syngenta Crop Protection	PAY PAY PAY	See endnote ³⁸
835.6200 (164-2)	Aquatic (Sediment) Field Dissipation Study				Not required ³⁹
835.6300 (164-3)	Forestry Field Dissipation Study				Not required
835.6400 (166-1)	Groundwater Monitoring				Not required
860.1300 (171-4(a))	Nature of the Residue in Plants	46012908	Syngenta Crop Protection	PAY	
860.1300 (171-4(b))	Nature of the Residue in Livestock	Cite-all		PAY	
860.1340 (171-4(c), (d))	Residue Analytical Methods	48693701	Syngenta Crop Protection	PAY	See endnote ⁴⁰
860.1360	Multiresidue Method	44755301	Syngenta Crop Protection	PAY	
860.1380 (171-4(e))	Storage Stability	Cite-all		PAY	
860.1400 (171-4(f))	Nature and Magnitude of the Residue in Drinking and Irrigation Water				Not required
860.1400 (171-4(g))	Magnitude of the Residue in Fish				Not required
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Ingredient Clodinafop-propargyl (CAS No. 105512-06-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1400 (171-4(h), 165-3)	Magnitude of the Residue in Plants Resulting from the Use of Irrigation Water				Not required
860.1480 (171-4(j))	Magnitude of the Residue in Meat, Milk, Poultry, and Eggs				Not required ⁴¹
860.1500 (171-4(k))	Magnitude of the Residue in Plants – Wheat	48693702	Syngenta Crop Protection	PAY	See endnote ⁴²
860.1520 (171-4(l))	Magnitude of Residue in Processed Food/Feed – Wheat	44755303	Syngenta Crop Protection	PAY	See endnote ⁴³
860.1850 (165-1)	Confined Crop Rotation Study	Cite-all		PAY	
860.1900 (165-2)	Field Rotational Crop				Not required
201-1	Droplet Size Spectrum	Cite-all		PAY	
202-1	Droplet Size Spectrum	Cite-all		PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date May 21, 2013

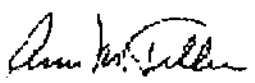
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Ingredient Clodinafop-propargyl (CAS No. 105512-06-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Generic Data Requirements					
NewAgco, Inc. will make offers-to-pay to the following companies on the data submitters list of September 27, 2012 for Clodinafop-propargyl.					
		Cite-all	Syngenta Crop Protection, LLC	PAY	
		Cite-all	Spray Drift Task Force	PAY	
		Cite-all	Outdoor Residential Exposure Task Force	PAY	
		Cite-all	Agricultural Reentry Task Force	PAY	
		Cite-all	FIFRA Endangered Species Task Force	PAY	
		Cite-all	Agricultural Handlers Exposure Task Force	PAY	
		Cite-all	Generic Endangered Species Task Force	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date May 21, 2013

Endnotes for Data Matrix for Clodinafop-Propargyl Technical

-
- ¹ **830.1650** - These data are not required for the registration of a technical grade active ingredient product. See 830.1620 for production process information.
- ² **830.6313** - Clodinafop-Propargyl Technical was found to be stable at normal and elevated (54°C) temperatures for 28 days. The data is found in Volume 7. NewAgCo, Inc. does not package Clodinafop-Propargyl Technical in metal containers, nor is Clodinafop-Propargyl Technical expected to come into contact with metals or metal ions during its storage or use and a waiver from this part of the data requirement is requested.
- ³ **830.6315** - NewAgCo, Inc. requests a waiver from the requirement of this data requirement since Clodinafop-Propargyl Technical is not expected to be flammable. Please refer to the Confidential Statement of Formula for Clodinafop-Propargyl Technical.
- ⁴ **830.6316** - NewAgCo, Inc. requests a waiver from this data requirement because clodinafop-propargyl does not have the chemical bonds or functional groups associated with explosive chemicals.
- ⁵ **830.6317, 830.6320** - Per PR Notice 92-5, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. NewAgCo, Inc. agrees to conduct these studies if required and requests that the studies be made a condition of registration.
- ⁶ **830.6319, 830.6321, 830.7100, 830.7520** - Clodinafop-Propargyl Technical is a solid and not an emulsifiable concentrate and is not to be diluted with petroleum solvents. Therefore, miscibility data are not required for this technical. Clodinafop-Propargyl Technical is not to be used around electrical equipment and data for dielectric breakdown constant are not required. Clodinafop-Propargyl Technical is a solid and not a liquid, therefore, viscosity data are not required for this product. NewAgCo Inc. is seeking a waiver for particle size, fiber length and diameter distribution because Clodinafop-Propargyl Technical is not water insoluble and it is not a fibrous material.
- ⁷ **830.7220** - Clodinafop-Propargyl Technical is a solid and boiling point data are not required for solids. Data for melting point are required for solids. See Guideline 830.7200.
- ⁸ **850.1025, 850.1035, 850.1045, 850.1055, 850.1075** - These data are not required per the Dec. 5, 2012 Preliminary Problem Formulation.
- ⁹ **850.1350** - These data are not required per the Dec. 5, 2012 Preliminary Problem Formulation.
- ¹⁰ **850.1400 (saltwater)** - These data are not required per the Dec. 5, 2012 Preliminary Problem Formulation.
- ¹¹ **850.1500** - These data are not required per the Dec. 5, 2012 Preliminary Problem Formulation.
- ¹² **850.3030** - These data are not required per the Dec. 5, 2012 Preliminary Problem Formulation.
- ¹³ **850.3040** - These data are not required per the Dec. 5, 2012 Preliminary Problem Formulation.
- ¹⁴ **870.6100** - According to the Nov. 15, 2012 Human Health Scoping Document for Registration Review, the studies cited fulfill the data requirement.
- ¹⁵ **870.3100** - According to the Nov. 15, 2012 Human Health Scoping Document for Registration Review, the studies cited fulfill the data requirement.
- ¹⁶ **870.3150** - According to the Nov. 15, 2012 Human Health Scoping Document for Registration Review, the study cited fulfills the data requirement.
- ¹⁷ **870.3200** - According to the Nov. 15, 2012 Human Health Scoping Document for Registration Review, the study cited fulfills the data requirement.
- ¹⁸ **870.3250** - According to the Nov. 15, 2012 Human Health Scoping Document for Registration Review, these data are not required.

Endnotes for Data Matrix for Clodinafop-Propargyl Technical

- ¹⁹ **870.3465** – According to the Nov. 15, 2012 Human Health Scoping Document for Registration Review, these data were identified as “conditionally required”, but that no data have been submitted to satisfy this guideline. In addition, the Sept. 13, 2012 HASPOC memo notes these data are not required.
- ²⁰ **870.6200** – According to the Nov. 15, 2012 Human Health Scoping Document for Registration Review, the studies cited fulfill the data requirement.
- ²¹ **870.4100** – According to the Nov. 15, 2012 Human Health Scoping Document for Registration Review, the study cited fulfills the data requirement.
- ²² **83-1(b)** – These data are no longer required under 40 CFR Part 158.
- ²³ **870.4200** – According to the Nov. 15, 2012 Human Health Scoping Document for Registration Review, the studies cited fulfill the data requirement.
- ²⁴ **870.3700** – According to the Nov. 15, 2012 Human Health Scoping Document for Registration Review, the studies cited fulfill the data requirement.
- ²⁵ **870.3800** – According to the Nov. 15, 2012 Human Health Scoping Document for Registration Review, the study cited fulfills the data requirement.
- ²⁶ **870.6300** – According to the Nov. 15, 2012 Human Health Scoping Document for Registration Review, the studies cited fulfill the data requirement.
- ²⁷ **870.5100, 870.5200** – According to the Nov. 15, 2012 Human Health Scoping Document for Registration Review, the studies cited fulfill the data requirement.
- ²⁸ **870.5550** – According to the Nov. 15, 2012 Human Health Scoping Document for Registration Review, the study cited fulfills the data requirement. Note MRID 44399155 was not cited because it is not considered acceptable.
- ²⁹ **870.5395** – According to the Nov. 15, 2012 Human Health Scoping Document for Registration Review, the study cited fulfills the data requirement. Note MRID 44399154 was not cited because it is not considered acceptable.
- ³⁰ **870.7485** – According to the Nov. 15, 2012 Human Health Scoping Document for Registration Review, the studies cited fulfill the data requirement.
- ³¹ **870.7600** – According to the Nov. 15, 2012 Human Health Scoping Document for Registration Review, these data are not required.
- ³² **835.2240** – According to the Dec. 5, 2012 Preliminary Problem Formulation for Registration Review, the studies cited fulfill the data requirement.
- ³³ **835.4100** – According to the Dec. 5, 2012 Preliminary Problem Formulation for Registration Review, the studies cited fulfill the data requirement. Note: 46012931 was listed twice in Table 7.1, but 46012930 is also mentioned throughout the document. Therefore, it appears that 46012930 was intended to be listed in addition to 46012931 in Table 7.1 of the Preliminary Problem Formulation.
- ³⁴ **835.4300** – According to the Dec. 5, 2012 Preliminary Problem Formulation for Registration Review, the studies cited fulfill the data requirement.
- ³⁵ **835.4400** – According to the Dec. 5, 2012 Preliminary Problem Formulation for Registration Review, the studies cited were classified as acceptable and appear to satisfy the data requirement.
- ³⁶ **835.1230, 835.1240** – According to the Dec. 5, 2012 Preliminary Problem Formulation for Registration Review, the studies cited appear to satisfy the data requirement. MRID numbers 44399179, 44399180 and 44399181 were not cited because these studies were classified as unacceptable. MRID number 44831201 was not cited because it was replaced by MRID number 46012937, which was cited. MRID number 44831202 was not cited because it was replaced by MRID number 46012934, which was cited.
- ³⁷ **835.1410** – These data are not required per the Dec. 5, 2012 Preliminary Problem Formulation.

Endnotes for Data Matrix for Clodinafop-Propargyl Technical

- ³⁸ **835.6100** – According to the Dec. 5, 2012 Preliminary Problem Formulation for Registration Review, the studies cited appear to satisfy the data requirement.
- ³⁹ **835.1410** – These data are not required per the Dec. 5, 2012 Preliminary Problem Formulation.
- ⁴⁰ **835.1340** – According to a Sept. 24, 2012 memorandum, MRID 48693701 supports the analytical method requirement for use of clodinafop on wheat.
- ⁴¹ **835.1480** – According to an April 7, 2000 memorandum, magnitude of the residue data are not required because of low residues found in the metabolism study.
- ⁴² **835.1500** – According to a Sept. 24, 2012 memorandum, MRID 48693701 supports the analytical method requirement for use of clodinafop on wheat.
- ⁴³ **835.1500** – According to an April 7, 2000 memorandum, the study satisfied satisfies the data requirement.



June 16, 2011

To Whom It May Concern:

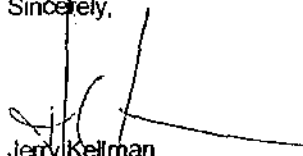
RE: Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Pyxis Regulatory Consulting, Inc. is authorized to act as agent for NewAgco Inc. (EPA Company Number 86794), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,



Jerry Kellman
Treasurer
NewAgco Inc.

cc: Pyxis Regulatory Consulting, Inc.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number NewAgCo Inc. c/o Pyxis Regulatory Consulting 4110 136th St. NW Gig Harbor, WA (253) 853-7385	EPA Registration Number/File Symbol 86794
Active Ingredient(s) and/or representative test compound(s) Clodinafop-propargyl	Date 5/24/13
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) TSAI	Product Name MPower Clodinafop-Propargyl Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

(Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility or compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study, and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 5/24/13	Typed or Printed Name and Title Ann M. Tillman, Agent
---------------	-----------------	--

[illegible]

Follow Up Flag:	Follow up
Flag Status:	Flagged

Your payment has been submitted to Pay.gov and the details are below. If you have any questions or you wish to cancel this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at pay.gov.clev@clev.frb.org.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25AR096E
Agency Tracking ID: 74452051151
Transaction Type: Sale
Transaction Date: May 20, 2013 6:33:49 AM

Account Holder Name: Ann Tillman
Transaction Amount: \$8,997.00
Billing Address: 4110 136th St. NW
City: Gig Harbor
State/Province: WA
Zip/Postal Code: 98832
Country: USA
Card Type: AmericanExpress
Card Number: *****1031

Decision Number:
Registration Number:
Company Name: NewAgco Inc.
Company Number: 86794
Action Code: R334

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 23, 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-479095
EPA File Symbol or Registration Number: 86794-U
Product Name: MPOWER CLODINAFOP-PROPARGYL TECHNICAL
EPA Receipt Date: 22-May-2013
EPA Company Number: 86794
Company Name: NEWAGCO, INC.

ANN M. TILLMAN
PYXIS REGULATORY CONSULTING, INC.
NEWAGCO, INC.
4110 136TH ST., NW
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Application and 50% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application, 50% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R334
NEW PRODUCT;MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OF THE ACTIVE
INGREDIENT;REQUIRES SCIENCE DATA REVIEW;NEW PHYSICAL FORM;SELECTIVE DATA CITATION;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "m. sh", is written over the word "Sincerely,".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{935877 ~

This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies? ☒ Fee Waiver?

☐ volpay % Reduction: 50

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 23

Receipt No.

S-

935877

EPA File Symbol/Reg. No.

86794-U

Pin-Punch Date:

5/22/2013

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R334

Granted: R334

Amount Due: \$ 17,993

Parent/Child Decisions:

86794-U

86794-L
R334.1
End use product

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: [Signature]

Date: 5/23/13

Remarks:

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 5-22-13

Experts In-Processing Signature: B. L.

Date 5-28-13

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>86794-U</u>		EPA Receipt Date: <u>5-22-13</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of <u>Label</u> (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>				X
	<u>Required Data</u> and/or data waivers. See Footnote C.				
10	a) List study (or studies) not included with application				

Comments:

* Technical & Impurities only, no inerts to review

Sacket Pass
11-03 Pass

FG

IRID 291333

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, **to obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

21-Day Screen Completed by
Contractor

21-Day Expires on 6-12-13

Jacket # 86794-U
MRID# 491333

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

STEPHEN SCHABER

linked
w/
86794-L
↓
withdrawn!

waiting on jacket
36794 - U
6/5/13

Memorandum

Date: 05/31/13

To: PM 23, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission

Completion of 21-Day Content Screen

PM- 23

EPA Reg. # (File Symbol) 86794-U

Decision # D

Data package delivered to
you on 6-20-13.
(date)

Jacket/Mini-jacket will be
transferred to you today.
(Pick up from Document Center)

Thank you,

Registration Division's 21-Day Content Team



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 31, 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

PYXIS REGULATORY CONSULTING, INC.
NEWAGCO, INC.
4110 136TH ST., NW
GIG HARBOR, WA 98332

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 22-MAY-13. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

There is an ELECTRONIC LABEL for this action

You can use Acrobat to compare the e-label to the previous version (and find the changes). You can also use Acrobat to mark-up the e-label with your comments.

If e-label was submitted via

CD-ROM with paper application

then you will find e-label in

Electronic Label Library

If the e-label is not found in the ELL then it was probably not named correctly and could not be entered into the ELL. However, the file can be retrieved from the CD which is retained by the Front End.

or

If e-label was submitted via

XML E-Submission (no paper)

then you will find e-label in

Documentum

See overview of processing e-labels on other side of this sheet.

If you have any questions on e-labels, please contact one of your division e-label experts:

AD

Willie Abney

308-1689

Renee Whitaker

308-7003

Tracy Lantz

308-6415

BPPD

RD

Tom Harris

308-9423



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number NewAgco Inc./86794-	2. EPA Product Manager K. Montague	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) NewAgco Inc./Mpower Clodinafop-Propargyl Technical	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) NewAgco Inc. c/o Pyxis Regulatory Consulting Inc. 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 100-909 Product Name Clodinafop Propargyl Technical	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This application falls under PRIA Category R334 (New MUP; unregistered source of active ingredient; selective data citation). NewAgco is requesting a 50% small business waiver of the \$17,993 PRIA fee. NewAgco has paid a fee of \$8,997. This application is linked to a secondary application for MPower Clodinafop Herbicide end use product.

Section - III

1. Material This Product Will Be Packaged in:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input checked="" type="checkbox"/> Other (Specify) lined fiber board drum	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 55.1, 110.2 lb		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)				
Name Ann M. Tillman		Title Agent		
		Telephone No. (Include Area Code) (253) 853-7369		
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)	
2. Signature 		3. Title Agent		
4. Typed Name Ann M. Tillman		5. Date 5/21/13		

FOR OFFICIAL USE ONLY

FILE SYMBOL
REGISTRATION NO. 86794-4

CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

DATE SUBMITTED	SUBMITTED BY (✓)	
	APPLICANT	BASIC SUPPLIER
05/22/83		

Do Not Write Comments,
Formula, or Parts of Formula
on This Envelope

NOTE

It shall be unlawful for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena, or to physicians, and in emergencies to pharmacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act."

Confidential Statement of Formula may be entitled to confidential treatment